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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,629	06/19/2001	Peter H. St. George-Hyslop	1034/1J800US1	3866

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EXAMINER
CHEN, LIPING

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/884,629	Applicant(s) ST. GEORGE-HYSLOP ET AL.	
	Examiner Liping Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 24-28, drawn to a transgenic non-human mammal whose genome comprises a transgene comprising a nucleotide sequence encoding a mutated heterologous amyloid precursor protein 695 (APP_{695}), the nucleotide sequence, a vector comprising the nucleotide and a method of producing the transgenic non-human mammal, classified in 800, subclass 8+.

II. Claims 8-19, drawn to a transgenic non-human mammal whose genome comprises a transgene comprising a nucleotide sequence encoding a mutated heterologous APP_{695}, and a second nucleotide sequence encoding a selected protein with at least one selected mutation, classified in 800, subclass 8+.

III. Claims 20-22, drawn to a method for screening a candidate compound for its efficacy in preventing or delaying the development of Alzheimer's Disease (AD), classified in class 435, subclass 4.

IV. Claim 23, drawn to a method for screening a candidate compound for its efficacy in ameliorating the symptoms of AD, classified in 435, subclass 4.

V. Claims 29-32, drawn to a method of reducing a cognitive deficit in a mammal by administering effective amount of Aβ peptide, classified in class 514, subclass 12.

VI. Claims 33-35, drawn to a method of using Aβ peptide to manufacture a medicament for reducing a cognitive deficit in a mammal, classified in class 435, subclass 2.

In addition, upon the election of group II, further election of the following patentably distinct species of the claimed invention is required:

Presenilin, a low-density lipoprotein receptor, a α2-macroglobulin, or a β-secretase.

The selected proteins are distinct because they are structurally, functionally distinct.

Upon the election of presenilin, further election one of the following species for examination purpose is required:

Presenilin 2 polypeptide M239V mutation, presenilin 1 polypeptide L286V mutation, or preseninlin 1 polypeptide M146L and L286V mutation.

Upon the election of group III or IV, further election of the following patentably distinct species of the claimed invention is required:

The transgenic animal from Group I or II, which include patentable distinct species election.

The inventions are distinct, each from the other because:

Groups I and II are distinct from each other because they are drawn to transgenic animals comprising different transgenes with different biological functions: a transgene encoding APP_{695}, or a transgene encoding APP_{695} and a second transgene encoding a selected mutant protein, which result in different non-human animals with different phenotypes, which require separate search. Search for the phenotype of a transgenic animal comprising mutated APP_{695} does not require search for the phenotype of a transgenic animal comprising APP_{695} and a second selected mutated protein, and vise versa. Further, although the transgenic animal of Group I can be used for making transgenic animal Group II, it can also be used for disease model. Thus, Group I and II are not obvious variants and deemed patentably distinct.

Groups III and IV are distinct from each other because they are drawn to different methods for detecting different compound: a candidate compound for preventing or delaying the development of AD, or a candidate compound for ameliorating the symptoms of AD, which requires different animal model and different technique for screening. These methods differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables,

criteria for success, and separate search. Thus, groups III and IV are patentably distinct from each other.

Groups V and VI are mutually exclusive and independent. The method of reducing a cognitive deficit in a mammal or human using Aβ peptide of Group V is not needed for the method of manufacture a medicament using Aβ peptide of Group VI, and vice versa. Each of the methods requires a separate and materially different protocol.

Groups I-II and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transgenic non-human animal of Group I or II can be used as disease model for the treatment study.

Groups I-II and Groups V and VI are mutually exclusive and independent. The transgenic non-human animal of Group I or II are not needed for the implementation of a method of reducing a cognitive deficit in a mammal or human using Aβ peptide of group V, or the method of manufacture a medicament using Aβ peptide of Group VI, and vice versa. Each of the methods requires a separate and materially different protocol.

Groups III-IV and Groups V and VI are mutually exclusive and independent. The screening method of groups III and IV are not needed for the implementation of a method of reducing a cognitive deficit in a mammal or human using Aβ peptide of group V, or the method of manufacture a medicament using Aβ peptide of Group VI, and vice versa. Each of the methods requires a separate and materially different protocol

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, because of their recognized divergent subject matter, and the search required for any group is not required for remaining groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Dianiece Jacobs, Patent Analyst, at (703) 305-3388. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632

PETER PARAS
PATENT EXAMINER